



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

HA

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/504,393      02/15/00      BACHMANN      H      20347/111656

EXAMINER

HM12/0828

Mark E Waddell Esq  
Bryan Cave LLP  
245 Park Avenue  
New York NY 10167-0034

PAK.Y  
ART UNIT      PAPER NUMBER

1652  
DATE MAILED:

//  
08/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/504,393

Applicant(s)

BACHMANN ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 16-18 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-15, 19-32 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed on August 3, 2001, amending the specification and claims and petition for extension of time, has been entered.

Claims 1-36 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Amendment***

Applicants argue that the specification identifies the utility of SEQ ID NO:1 as a participant in the pathway leading to the production of vitamin A (Remarks, page 5, 1<sup>st</sup> paragraph). Examiner disagrees. The starting material needs to be taught because there are many pathways leading to the production of vitamin A without any teachings on the substrate specificity. The specification teaches that of  $\beta$ -carotene by  $\beta$ , $\beta$ -carotene 15,15'-dioxygenase results in two moles of retinal. This reaction will have different results with a polypeptide having the current identification,  $\beta$ , $\beta$ -carotene 15,15'-monooxygenase activity.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-36 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The claimed polynucleotides are not supported by either a specific and substantial asserted utility. Applicants state that subsequent studies revealed the function of the enzyme represented by SEQ ID NO:1 is a  $\beta,\beta$ -carotene 15,15'-monooxygenase rather than a  $\beta,\beta$ -carotene 15,15'-dioxygenase (Remarks, page 4, 2<sup>nd</sup> paragraph). Applicants argue that the structure of an enzyme determines the function. However, the specification teaches that SEQ ID NO:1 has  $\beta,\beta$ -carotene 15,15'-dioxygenase activity (page 1, lines 25-27). Therefore, the specification does not teach the function of SEQ ID NO:1. Further, the  $\beta,\beta$ -carotene 15,15'-monooxygenase activity of SEQ ID NO:1 is unpredictable in the art because SEQ ID NO:1 has homology with polypeptides with  $\beta,\beta$ -carotene 15,15'-dioxygenase activity. These claims amount to a polypeptide with unknown function and a polypeptide with unknown and unpredictable function has no utility. Therefore, there is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding SEQ ID NO:1.

*page 23 - homology w/ d<sup>1</sup>*

#### ***Claim Rejections - 35 USC § 112***

Claims 6-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1652

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. The specification does not teach the function of the polypeptide encoded by SEQ ID NO:2 because the specification does not teach the correct function of the polypeptide. In the state of the art, the function of a polypeptide is unpredictable from its structure and the functionality of a polypeptide must be known in order to use the polypeptide. Therefore, the specification does not teach how to use SEQ ID NO:1 and DNA molecules encoding SEQ ID NO:1 without undue experimentation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorbjornsen et al.

Thorbjornsen et al. teach a DNA molecule that comprises bases 1-36 of SEQ ID NO:2. Therefore, the DNA molecule of Thorbjornsen et al. anticipates claims 7-9.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3173.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

August 21, 2001

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600